

Attorney Docket No.: **KUZ-0021**
Inventors: **Suzuki et al.**
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REMARKS

Claims 1-12 were pending in the instant application. Claims 1-12 have been rejected. Claims 1-2 have been canceled. Subject matter of these claims is represented in new claims 13 and 14. Dependent claims 3-11 have been amended to depend from claim 13. New claim 15 has also been added. Support for these amendments is provided in the specification at page 6, line 14 through page 7, line 3, page 9, line 26 through page 10, line 24, page 11, lines 2-4, and the Examples beginning at page 22. No new matter has been added by these amendments and entry is respectfully requested. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Objection to Abstract

Objection to the Abstract as lacking clarity was maintained in the Office Action mailed October 3, 2008. However, upon further review during the telephone interview on January 30, 2009, Examiner Palenik and Examiner Woodward agreed that the amendments to the Abstract were sufficiently clear. However, Examiner Woodward advised that the amended Abstract must be set forth on a separate sheet. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are submitting herewith a separate

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sheet containing the amended Abstract. Support for this amendment is provided in the specification at page 11, lines 2-4.

No new matter is added by this amendment.

Withdrawal of this objection is respectfully requested.

II. Obviousness-type Double Patenting Rejection of Claims 1, 6-9, 11 and 12 and Rejection of Claims 1-12 under 35 U.S.C. 103(a)

The rejection of claims 1, 6-9, 11 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-8 of Chono et al. (U.S. Patent 6,139,866) in view of claim 5 of Wick et al. (U.S. Patent 6,129,929) has been maintained.

The rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Wick et al. has also been maintained.

The Examiner suggests that in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to prepare a transdermal patch formulation comprising a silica-roughened backing layer and a drug-containing adhesive layer for percutaneous delivery of a drug from the adhesive layer with a reasonable expectation of success. At page 6 of the Office Action, the

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Examiner states that "Chono does not teach surface roughness." However, at page 5 of the Office Action, the Examiner states that "Wick et al. teaches the use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness the inclusion of which increase the friction between the backing layer and adhesive layer allowing for greater stability of the overall formulation." As page 7 of the Office Action, the Examiner relies upon teachings in Wick et al. at col. 4, lines 7-9 and col. 3, lines 63-65 to state that Wick et al. teaches "[t]he formulation can be treated (e.g. "sand blasted or sprayed) with fumed silica, reagent grade sand, or precipitated silica (col. 4, lines 7-9) to convey rheological properties, although it is acknowledged that multiple functions or properties (i.e. surface roughness) can be obtained through use of peripheral agents to the formulation (column 3, lines 63-65)."

Applicants respectfully traverse these rejections.

As discussed during the Telephone Interview on January 30, 2009, the claims have been amended to clarify a distinguishing structural characteristic of the polyester-based film of the instant invention. Specifically, the claims have been amended to recite that a side of said polyester-based film surface in contact with the drug-

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containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate. Support for this amendment is provided in the specification at page 6, line 14 through page 7, line 3, page 9, line 26 through page 10, line 24, page 11, lines 2-4, and the Examples beginning at page 22.

As also discussed during the Telephone Interview, neither of the cited references teaches or suggests roughening of the surface of the polyester-based film in contact with the drug containing adhesive layer. It was agreed during the Telephone Interview that if the combined references did not teach or suggest a polyester-based film with a side in contact with the drug-containing adhesive with a surface roughness (Ra) as claimed, the references could not render obvious the instant claimed invention.

The Examiner acknowledged at page 6 of the Office Action that Chono does not teach surface roughness.

Further, as discussed during the Telephone Interview, Wick et al. specifically teach at col. 3, lines 49-50 that "[t]he layers of transdermal patch 2, **other than the backing layer 2a**, can also contain agents . . ." (emphasis added).

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Accordingly, Wick et al. makes clear that agents taught at col. 4, lines 7-9 are **not** added to the polyester-based film backing layer. Thus, this reference also fails to teach or suggest a backing layer such as polyester-based film with a roughened side as claimed.

Further, Applicants have specified in the claim that the side of the polyester-based film has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate. The cited combination of references, neither of which teach or suggest roughening of the surface of the polyester-based film in any manner, clearly provide no reasonable expectation of success with respect to the enhanced anchoring properties and absence of pinholes of the instant claimed patch of the present invention.

Accordingly, the cited combination of references provides neither the required teaching or suggestion of claim limitations nor the reasonable expectation of success required to render obvious under either 35 U.S.C. 103(a) or obviousness-type double patenting the instant claimed invention. Withdrawal of these rejections is therefore respectfully requested.

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III. Rejection of Claims 1-12 under 35 U.S.C. 112, first paragraph

Claims 1-12 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the claimed units of "μmRa" are not discussed in a clear and concise manner.

As discussed during the Telephone Interview of January 30, 2009, the term "Ra" refers to surface roughness. This is supported by teachings of the specification at page 11, lines 2-4. It was agreed during the interview that placement of this term following the units of "μm", as opposed to the term "surface roughness" was an inadvertent error which occurred during translation.

Accordingly, in an earnest effort to clarify units of surface roughness Ra, Applicants have amended the specification and claims to recite "a surface roughness (Ra)" with "μm" as the units. No new matter is added by these amendments.

Withdrawal of this rejection is respectfully requested.

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**IV. Rejection of Claims 1-8 and 10-12 under 35 U.S.C.
102(b)**

Claims 1-8 and 10-12 have been rejected under 35 U.S.C. 102(b) as being anticipated by Chono et al. (U.S. Patent 6,139,866).

Applicants respectfully traverse this rejection.

MPEP 2131 and the case law are clear; a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "

As discussed in Section II, *supra*, claims of the instant application have been amended to recite a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer laminated thereon, wherein a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate.

The Examiner acknowledged at page 6 of the Office Action that Chono does not teach surface roughness.

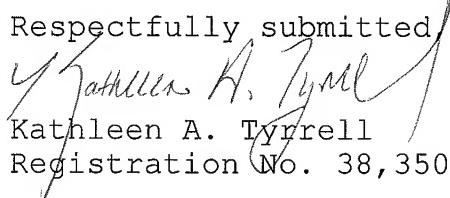
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Accordingly, this reference neither expressly nor inherently describes the claimed element of a polyester-based film having a side in contact with the drug-containing adhesive with a surface roughness (Ra) of from 0.05 to 0.8 μm . Accordingly, this reference cannot anticipate the instant claimed invention. See MPEP 2131.

Withdrawal of this rejection is respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted

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Date: **February 3, 2009**

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